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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,485	04/19/2004	Makarand P. Gore	200315628-1	3286

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EXAMINER
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MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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08/17/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/827,485	<b>Applicant(s)</b> GORE, MAKARAND P.	
	<b>Examiner</b> MELISSA S. MERCIER	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9-15, 17-24 and 26-49 is/are pending in the application.
- 4a) Of the above claim(s) 19-44 and 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-15, 17-18, 45-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicants Remarks and Amended Claims filed on June 8, 2010 is acknowledged. Claims 1-5, 9-15, 17-24, 26-49 remain pending in this application. Claims 19-44 and 47-49 remain withdrawn and Claims 1-5, 9-15, 17-18, and 45-46 remain under prosecution.

### ***Withdrawn Rejections/Objections***

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 3, 10, and 15 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of Applicants amendments to the claims to remove the phrases "derivatives thereof" and "non-acrylic polymer".

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants amendment to the claims to remove the phrase "including".

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1-4, 9-10, 13-15 and 45-46 under 35 U.S.C. 102(a) and (e) as being anticipated by Dennis et al. (US Patent 6,623,765) has been withdrawn in view of Applicants amendment to the claim to additionally require a drying agent to the jettable solution.

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The rejection of claims 1, 5, 13-15, and 45-46 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Owen et al. (US Patent 5,633,226) has been withdrawn in view of Applicants amendment to the claims to additionally require a drying agent to the jettable solution.

***Claim Rejections - 35 USC § 103***

The rejection over claims 1-3, 10, 13-15, 17, and 45-46 under 35 U.S.C. 103(a) as being unpatentable over Barreto (US Patent 7,166,154) has been withdrawn in view of Applicants statement that the subject matter, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person, i.e. HP.

The rejection of claims 11-12 under 35 U.S.C. 103(a) as being unpatentable over Barreto (US Patent 7,166,154) in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between, see IDS) has been withdrawn for the same reasons as Barreto alone.

***Newly Applied Rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 9-15, 17-18, and 45-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the independent claims to further comprise a drying agent. However, while the specification in paragraph 0033 discloses a drying agent can be included, there is no disclosure of examples of what a drying agent is. The component is defined by a functional property and not a structural element. The term drying agent is not defined in the specification and is unclear if the agent is intended to be a desiccant type agent or an agent that causes drying to the skin, such as numerous surfactants, as it appears applicant is attempting to argue against the Owen reference by citation of the disclosure in column 14, which recites the topical formulation is non-drying to the skin, not a formulation that stays wet to the touch indefinitely.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 10, 15, 17, and 45-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Ma et al. (US 6,790,435), as evidenced by The Merck Manuals, Diagnosis and Treatment of Skin Disorder.

Ma discloses an antiperspirant composition comprising micro-emulsions containing cosmetic oils, antiperspirant salts, water, and combinations of cationic quaternary ammonium salts. The micro emulsions can be in the form of roll-ons, aerosol and non-aerosol spray applicators (abstract). The micro emulsions are primarily composed of discontinuous phase but the composition include water in oil, oil in water, and micro emulsions gels (column 2, line 62 through column column 3, line 1). The viscosity of the micro emulsions can range from thick gels to low viscosity spray able liquids with viscosities under 10 cst (column 3, lines 26-28). The antiperspirant is an astringent active salt (column 4, lines 34-36). Astringents are drying agents, as evidenced by the article Diagnosis and Treatment of Skin Disorders.

Antimicrobial agents can be added (column 5, lines 44-46), which is a claimed pharmaceutical agent. Amino acids are also disclosed.

The oil phase can comprise mineral oils, fatty acid esters (column 6, lines 7-17). The non-ionic surfactant including methyl glycoside dioleante (column 13, line 1) as disclosed.

Additional components including emollients (column 5, line 61-63) and glycols (column 5, lines 44-48), can be added. It is noted by the Examiner that

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both emollients and glycols are art recognized rheology and viscosity modifying agents.

Ma does not disclose the viscosity is less than 5 centipose and has a surface tension of approximately 25-60 dynes per centimeter.

It would have been obvious to one of ordinary skill in the art to have modified the viscosity and surface tension of the composition through routine experimentation. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ma et al. (US 6,790,435), as evidenced by The Merck Manuals, Diagnosis and Treatment of Skin Disorder, in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between, see IDS).

The teachings of Ma are discussed above and applied in the same manner.

Ma does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino

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acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Ma because these naturally occurring fatty acids and amino acids are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore, determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

Claims 1-5, 9-10, 13-15, 17, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aust (US 2002/0143072) as evidenced by as evidenced by The Merck Manuals, Diagnosis and Treatment of Skin Disorder.

Aust discloses a micro emulsion containing one ore more pharmacological or cosmetic agents (abstract). The emulsions can be oil in water or water in oil. In a preferred embodiment, the pharmacological or cosmetic agent is included in the oil phase (paragraph 0015). The pharmacological agents include antimicrobial, anti-inflammatory, vitamins, astringents, anti-acne agents, and antipseboratic agents (paragraphs 0055-0071). It is noted by the Examiner and evidenced by the Article Diagnosis and Treatment of Skin Disorders, that anti-acne and astringents are drying agents.



Preferred oils include vegetable oils including soybean oil. Other useful oils include castor oil, safflower oil, and cottonseed oil (paragraph 0030).

The emulsion forms micelles (paragraph 0023). Suitable surfactants include non-ionic, anionic, or cationic surfactants or emulsifier is added to the oil- or water-phase prior to emulsification. Exemplary types of nonionic surfactants include silicone polyether's, both grafted and linear block, ethoxylated fatty alcohols, ethoxylated alcohols, ethoxylated alkyl phenols, Isolaureth-6 (polyethylene glycol ether of branched chain aliphatic C.sub.12-containing alcohols having the formula  $C_{12}H_{25}(OCH_2CH_2)_6OH$ , fatty acid alkanolamides, amine oxides, sorbitan derivatives, for example (paragraph 0042).

Additional adjuvant includes conditioning agents, which are humectants, colorants, gelling agents, viscosifiers, for example (paragraph 0082).

Aust does not disclose the viscosity is less than 5 centipose and has a surface tension of approximately 25-60 dynes per centimeter.

It would have been obvious to one of ordinary skill in the art to have modified the viscosity and surface tension of the composition through routine experimentation. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

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Claims 11-12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aust (US 2002/0143072) as evidenced by as evidenced by The Merck Manuals, Diagnosis and Treatment of Skin Disorder in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between, see IDS).

The teachings of Aust are discussed above and applied in the same manner.

Aust does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Aust because these naturally occurring fatty acids and amino acids are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore, determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 10, 13, 15, and 45-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13-14,16,and 21 of U.S. Patent No.7,166,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ by the addition of an active agent in the ink formulation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated an active agent into the printable ink as instantly claimed because Barreto discloses that such an additional can be included. It is further noted that the Barreto claims contain comprising terminology allowing for such an inclusion.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615